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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--------------------------------------|----------------------|---------------------|------------------|
| 10/554,974 | 03/02/2006 | Toshiyuki Takagi | SNKYO126511 | 9465 |
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| SUITE 2800 SEATTLE, WA | SUITE 2800 SEATTLE, WA 98101-2347 | | | PAPER NUMBER |
| , | | | 1614 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/28/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Claims 13, 14, 19-22, 25, 26 and 31-35 are presented for examination.

Applicants' amendment and response filed June 30, 2008 have been received and entered.

Accordingly, the rejection made under 35 USC 112, first paragraph (Written Description) as set forth in the previous Office action dated March 28, 2008 at pages 3-5 as applied to claims 32 and 34 is hereby withdrawn because the applicants cancelled claims 32 and 34.

Claims 14, 19-22, 26 and 30 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13, 25 and 33 are again provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 41,

43-47, 57, 59 and 60 of copending Application No. 10/555,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because of record, for reason of record as set forth in the previous Office action dated March 28, 2008 at pages 2-3 as applied to claims 13, 25, 32 and 33 is hereby **MAINTAINED**.

Claims 13, 25 and 33 are not allowed.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 25 are again rejected under 35 U.S.C. 102(b) as being anticipated by Freeman et al., Circulation of PTO-1449, of record, for reason of record as set forth in the previous Office action dated March 28, 2008 at pages 5-6 as applied to claims 13 and 25.

Applicants' remarks regarding the Freeman et al. reference's teaching the administration of pravastatin "beneficially affected glucose and insulin transport" is not the same as "enhancing glucose uptake" are not persuasive since the cited reference does teach the mechanism of producing glucose transport. It does not matter how or where the instant "mechanism" is produced, "glucose uptake" has the same characteristics of "glucose transport".

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The rejection made under 35 USC 102(b) is adhered to.

Claims 13 and 25 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-35 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al., Circulation of PTO-1440 in view of Weiner et al. (5,643,868) and further in view of Paolisso et al., European Journal of Clinical Pharmacology, Vol. 40, No. 1, pp. 27-31 (1991), all of record, for reason of record as set forth in the previous Office action dated March 28, 2008 at pages 5-7 as applied to claims 31-35.

Applicants' remarks regarding the prior art does not teach or suggest the combination of instant active agents are not persuasive since KSR forecloses the remarks that a **specific** teachings, suggestion, or motivation is required to support a

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finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd,. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396).

The rejection made under 35 USC 103(a) is adhered to.

Claims 31-35 are not allowed.